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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,545	11/14/2008	Giles Albert Brown	13425-192US1 BV-1087 US	3942
26161 7590 05/29/2009 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER CRANE, LAWRENCE E	
			ART UNIT	PAPER NUMBER
			1623	
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			05/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/581,545	Applicant(s) BROWN ET AL.	
	Examiner Lawrence E. Crane	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on June 2, 2006 (preliminary amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 and 40-44 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1,3,5-8,10-13,15-17,19-38 and 40-44 is/are rejected.
- 7) ☒ Claim(s) 2,4,9 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

The Abstract of the Disclosure is objected to because it does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

Applicant is respectfully requested to amend the abstract because the Abstract is not in US format and is also excessively brief.

Claim **39** has been cancelled, claims **3, 5, 7, 11, 13, 22-24, 26, 30, 32, 35 and 36** have been amended, the disclosure has been amended at page 1, and no new claims have been added as per the preliminary amendments filed June 2, 2006. One Information Disclosure Statement (1 IDS) filed October 30, 2006 has been received with all cited references and made of record.

Claims **1-38 and 40-44** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line **y**, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

35 U.S.C. §101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

Claims **7, 13, 15-17, 20 and 41** are rejected under 35 U.S.C. §101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim

under 35 U.S.C. §101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App., 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149, 149 USPQ 475 (D.D.C. 1966).

In each of claims **7, 13, 15-17, 20 and 41** the term “using” or the term “Use” appear and should be replaced with alternative language in order to fully describe the process steps implied by the present terminology.

The disclosure is objected to because of the following informalities:

The contents of Scheme 1 and Scheme 2 at pages 20 and 21 are legible but in need of amendment to correct spelling errors: e.g. see Scheme 2 wherein the root “adenosine” is misspelled once. In addition, the quality of the Scheme’s structures is rough and both Schemes need to be resubmitted in amended form wherein these problems have been addressed.

Appropriate correction is required.

Claim **19** is objected to because of the following informalities:

In claim **19** the term “ntiro” is a misspelling of the prefix
-- nitro --.

Appropriate correction is required.

Claims **1, 3, 5, 6, 8, 10-12, 19, 20, 22, 25-30, 32-34, 41 and 43-44** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at line 2, the term “converting” standing alone is insufficient to adequately describe the process step or steps required to execute the claimed process wherein 2-nitropentabenzoyladenine is converted into the variety of 2-substituted adenosines encompassed by the subject matter disclosed at lines 3-8. See also claims **3** (“converted ... by deprotection”), **5, 6, 11, 12 and 22** (“produced ... by deprotecting”) wherein the same or similar errors reoccur.

In claim **8** the term “reducing the amount of TBAN or TMAN” is incomplete because the process step or steps being claimed have not been adequately described. See also claim **20** at lines 3-4 wherein the same error reoccurs.

In claim **10** the term “recrystallising” is a process step but has not been completely described because the presence of a solvent or solvents have not been included in the claim. See also claim **19** wherein the same error reoccurs.

In claim **22** at lines 1-3, it is unclear whether the “deprotecting” and the “reaction with ... alkoxide anion or phenoxide anion” are both happening simultaneously courtesy of the named reagents. Either a clarifying explanation or an amendment is respectfully requested.

In claim **25** the term “acylated” appears twice but, because the products of the two process steps claimed are different, the process conditions must be different. Clarification of the obviously differing meanings of the term “acylating” is respectfully requested. See also claims **27, 29 and 43** wherein the same problem reoccurs.

In claim **26** the term “washing” is generic with no particular details of the actual process step having been specified, and therefore the claimed process step is incompletely described. See also claims **28, 29 and 44** wherein the same error reoccurs.

In claim **27** the term “formula 1” is incompletely defined because there is no chemical formula present in the claim. See also claim **29** wherein the same error reoccurs.

In claim **27** at line 4, the term “producing the 2-substituted adenosine” is incomplete because the particular structure(s) being synthesized have not been specified and the process for making these compounds have also not been disclosed within the claim. See also claim **28** wherein the same error reoccurs. See also claims **28-30** wherein the same error reoccurs.

In claim **30** the term “nitrating” is incomplete because -- the reagent(s) -- required to effect this process step(s) has(have) not been disclosed in the claim, thereby rendering the claim incomplete.

In claim **32** the process step whereby 2-nitroadenosine is converted into 2-chloroadenosine is claimed, but has not been described, thereby rendering the instant claimed process incompletely described in this claim. See also claims **33 and 34** wherein the same or a very similar error reoccurs.

Claim **38** makes reference to process details in Schemes 1 and 2, details not found in the claim, and therefore said claim is incompletely described.

In claim **41** the acronyms “TBAN” and “TMAN” are incomplete because the complete chemical names referred to thereby have not been include: e.g. -- 3’-azido-3’-deoxythymidine (AZT) --.

In claim **41** at lines 3-4, the term “reducing” implies a process step that has not been described with sufficient detail, thereby rendering this process step incompletely described in this claim. See also claim **44** wherein the same error reoccurs.

In claim **43** at line 2, the term “includes” is not a judicially recognized term of art in patent claims. Did applicant intend to provide the term -- comprises --? See also claim **44** wherein the same error reoccurs.

In claim **43** at lines 1-2 refers to three different processes, but has failed to describe how the subject matter at line 3-4 fits into these processes,.thereby rendering the claim both confusing and incomplete. See also claim **44** wherein the same error reoccurs.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

“A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.”

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.”

(c) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).”

(f) he did not himself invent the subject matter sought to be patented.”

Claims **36 and 40** are rejected under 35 U.S.C. §102(b) as being anticipated by **Degheti et al.** (PTO-1449 ref. **AG**).

Claim **40** and in part claim **36** are directed to the compound 2-methoxyadenosine. That claim **36** is a product by process claim does not negate the effectiveness of any reference that discloses a specific compound that reads on the claimed subject matter regardless of the process of synthesis because the process of synthesis of a specific compound does not continue to be a part of said compound once said synthesis has been completed. See also newly cited PTO-892 references Marumoto et al (**R**), Ueeda et al. (**I**) (**S**), and Ueeda et al. (**II**) (**T**) wherein there are numerous 2-alkoxyadenosine compounds disclosed each of which also anticipates the subgeneric genus defined in claim **36**.

Claims **20-35, 37, 38 and 41-44** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Degheti et al.** (PTO-1449 ref. **AG**).

Applicant is referred to page 1292, Scheme 1, and associated explanatory text wherein substrate 6 is nitrated to yield product 14 when contacted with tetrabutylammonium nitrate in the presence of trifluoroacetic anhydride, with subsequent deprotection yielding a mixture of 2-nitroadenosine and 2-methoxyadenosine. This prior art disclosure anticipates the instant claimed subject matter.

Claim **14** appears to be allowable as submitted.

Claims **1, 3, 5-7, 10-13 and 15-17** would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. §101 and 35 U.S.C. §112 set forth in this Office action.

Claims **2, 4, 8, 9, 18 and 19** are objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
05/25/2009

/Lawrence E. Crane/

Primary Examiner, Art Unit 1623

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